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Applicants	Heath, et al.		
Serial No.	09/361,829		
ling Date	July 27, 1999		
Group Art Unit	1631		
Examiner Name	J. S. Lundgren		
Attorney Docket No.	101.003US01		

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TECH CENTER 1600/29

Title: COMPUTER IMPLEMENTED NUCLEIC ACID ISOLATION METHOD AND APPARATUS

Commissioner for Patents Box Non-Fee Amendment Washington, D.C. 20231

Enclosures

The following documents are enclosed:

Amendment and Response (4 pgs.)

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TECH CENTER 1600/2900 PATENT

IE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

S/N 09

Heath, et al.

Examiner:

Jeffrey S. Lundgren

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AMENDMENT AND RESPONSE

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In response to the Office Action mailed April 4, 2001, Applicant responds as follows:

REMARKS

Rejections Under 35 U.S.C. § 103

Claims 1-7, 9-10 and 14-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson et al. (U. S. Patent No. 5,773,221) in view of Kelley et al. (U. S. Patent No. 5,679,154), in view of Vogel et al. (U. S. Patent No. 5,922,320) in view of Pfost et al. (U.S. Patent No. 5,369,566) in view of Bacus et al. (U.S. Patent No. 4,175,860).

Applicant notes that the Office Action withdraws the rejections contained in the previous Office Action in favor of new rejections on new art. The third cited reference, Vogel et al., is said to disclose manipulating or transferring nucleic acids by aspiration for the advantages of not shearing. Applicant submits that the art is of two different voices on the matter. The motivation to combine Vogel into the rejection is indicated to be reduction in shear forces that could damage a nucleic acid sample. However, the art is of two voices, since shearing sometimes is used and sometimes not used. For example, in the present claimed invention, the mixing speed is not indicated. The specification indicates that the mixing speed can be varied depending upon the degree of mixing desired by the user. See specification page 6, lines 27-29:

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"Mixing is accomplished at various levels from gentle to vigorous. Mixing may be accomplished by any number of processes including physical agitation and a combination of aspirating and dispensing."

Gentle mixing allows the sample being mixed to avoid shearing. However, the vigorous mixing also indicated in the specification allows shearing to occur. The automated processes and apparatuses of the claimed invention allow the control of such mixing to accomplished either shearing or no shearing as is required or desired by the user or the process. This controlled release and controlled aspiration allows control over shearing versus non-shearing forces in the claimed processes and apparatuses. For this reason, the combination of references including Vogel teaches but one aspect of the present claims. Indeed, the cited references do no recognize all the advantages of the claimed automated system.

The rejection appears to take one of two potential paths. The art itself is of two opinions, namely the advantages of non-shearing mixing and of shearing mixing. Because the art is of two different voices, it is an arbitrary choice made to follow one path or the other in the rejection. There is therefore no motivation to combine the references in the manner they have been combined. It is happenstance why the Office Action chooses one available path over the other path. For example, the Vogel et al. reference teaches gentle aspiration to avoid shearing. However, shearing is used in nucleic acid aspiration in many ways, for example by vigorous pipetting. U.S. Patent No. 5,863,755 (Schlessinger et al.) teaches some of the advantages of shearing as they relate to DNA. See Schlessinger, column 25, lines 52-58:

The purified cDNA is fragmented (by shearing, endonuclease digestion, etc.) to produce a pool of DNA or cDNA fragments. DNA or cDNA fragments from this pool are then cloned into an expression vector in order to produce a genomic or cDNA library of expression vectors whose members each contain a unique cloned DNA or cDNA fragment.

Further, Applicant reiterates its contention that Bacus is not proper art to be contained in a rejection. The Office Action asserts that Bacus teaches a method and an automated laboratory apparatus for performing the method, and how automation is advantageous over

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high-throughput, human-performed, laboratory methods, and cites for support column 1, lines 31-59 of Bacus. A reading of Bacus indicates that Column 1, lines 31-59 is a detailed analysis of 20 years of failure in such endeavors, not successes. Further, Bacus, at Column 1, lines 39-39, indicates that automation might be advantageous, but goes on to detail how it has not been advantageous in lines 40-59. Applicant is unaware how a list of automation failures is proper support for automation. Applicant's full arguments will not be repeated herein for purposes of brevity.

Applicant respectfully submits that claims 1-7, 9-10, and 14-18 are allowable.

Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost and Bacus, and further in view of Thrush et al. (U. S. Patent No. 5,692,144). Claim 8 depends from and further defines patentably distinct claim 6, and is also believed allowable.

Claims 11 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost and Bacus, and further in view of Johnson et al. (U. S. Patent No. 5,584,039). Claims 11 and 19 depend from and further define patentably distinct claims 9 and 14, respectively, and are also believed allowable.

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost and Bacus, and further in view of Poulter et al. (U. S. Patent No. 6,072,795). Claim 12 depends from and further defines patentably distinct claim 9, and is believed allowable.

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost and Bacus, and further in view of McNutt (U. S. Patent No. 5,802,389). Claim 13 depends from and further defines patentably distinct claim 9, and is believed allowable.

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CONCLUSION

Claims 1-19 remain pending in the application. Applicant believes that all of the claims are in condition for allowance and respectfully requests a Notice of Allowance be issued in this case. If the Examiner has any questions regarding this application, please contact the undersigned attorney at (612) 312-2203.

Respectfully submitted,

Date: 3July 200/

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